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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night;

Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces a meeting to peer review the Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night. NTP has conducted a literature-based assessment to determine whether night shift work (e.g., working at least three hours between 12 AM and 6 AM) and light at night are cancer hazards and should be listed the Report on Carcinogens. The peer-review meeting will be held at the National Institute of Environmental Health Sciences (NIEHS) in Research Triangle Park, NC and is open to the public. Registration is requested for attendance at the meeting either in-person or by webcast and to present oral comments. Information about the meeting and registration is available at https://ntp.niehs.nih.gov/go/36051.

**DATES:** Meeting: Scheduled for October 5, 2018, 8:30 a.m. to adjournment at approximately 5:00 p.m. Eastern Daylight Time (EDT). The preliminary agenda is available at <a href="https://ntp.niehs.nih.gov/go/36051">https://ntp.niehs.nih.gov/go/36051</a> and will be updated one week before the meeting.

Document Availability: The draft RoC monograph should be available by August 24, 2018, at https://ntp.niehs.nih.gov/go/36051.

Written Public Comment Submissions: Deadline is September 21, 2018.

Registration for Oral Comments: Deadline is September 21, 2018.

Registration to Attend Meeting In-person or to View Webcast: Deadline is October 5, 2018.

**ADDRESSES:** Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Webpage: The draft RoC monograph, preliminary agenda, registration, and other meeting materials will be available at <a href="https://ntp.niehs.nih.gov/go/36051">https://ntp.niehs.nih.gov/go/36051</a>.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

**FOR FURTHER INFORMATION CONTACT:** Kate Helmick, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293-1673, Fax: (919) 293-1645, Email: <a href="https://www.nchar.nchar.org/nchar.nchar.org/nchar.org/nchar.nchar.org/nchar

## SUPPLEMENTARY INFORMATION:

Background: The invention of electric light transformed society, from one in which people's activities and sleep patterns were limited by the natural light:dark cycle to a culture in which people now work, sleep, eat, and receive goods or services throughout the 24-hour day. Through lifestyle choices, home location, and work schedule, people are exposed to different patterns and types of light, including electric light at night (LAN), which may lead to cancer and other adverse health effects. These health effects may arise from misalignment of daily physiological and behavioral cycles (i.e., circadian rhythms) with external stimuli or with each other (i.e., circadian disruption). Circadian

rhythms can include processes and behaviors like sleep-wake cycles, eating, and body temperature, among others.

NTP has conducted a literature-based assessment and applied the Report on Carcinogens (RoC) listing criteria to this assessment to determine whether night shift work (e.g., working at least three hours between midnight and 6 AM) and light at night are cancer hazards. As circadian disruption is thought to be a key intermediate step, NTP has also reviewed the literature on this topic.

The monograph assesses the evidence from cancer studies in humans and experimental animals and mechanistic data and provides NTP's preliminary recommendation regarding whether night shift work and or light at night should be listed in the Report on Carcinogens, and if so, how the two exposure scenarios should be defined. The listing categories include *known or reasonably anticipated to be a human carcinogen*.

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment; in-person attendance at the NIEHS is limited by the space available (~100 attendees). Registration for in-person attendance is on a first-come, first-served basis. After the first 100 registrants, persons will be placed on a wait list and notified should an opening become available. Registration to attend the meeting in-person or view the webcast is by October 5, 2018, at <a href="https://ntp.niehs.nih.gov/go/36051">https://ntp.niehs.nih.gov/go/36051</a>. The URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in person is available at <a href="https://www.niehs.nih.gov/about/visiting/index.cfm">https://www.niehs.nih.gov/about/visiting/index.cfm</a>. Individuals with disabilities who need accommodation to view the webcast should contact Kate Helmick by phone: (919)

293-1673 or email: <a href="MTP-Meetings@icf.com">MTP-Meetings@icf.com</a>. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Public Comment Registration: NTP invites written and oral public comments on the draft RoC monograph that address scientific/technical issues. Guidelines for public comments are available at

https://ntp.niehs.nih.gov/ntp/about\_ntp/guidelines\_public\_comments\_508.pdf.

The deadline for submission of written comments is September 21, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific/technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

The agenda allows for one oral public comment period (up to 12 commenters, up to 5 min per speaker). Registration to provide oral comments is September 21, 2018, at <a href="https://ntp.niehs.nih.gov/go/36051">https://ntp.niehs.nih.gov/go/36051</a>. Registration is on a first-come, first-served basis. Each organization is allowed one time slot. Oral comments may be presented in person at NIEHS or by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified after September 21, 2018, the deadline to register for oral public comments, about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Kate Helmick by email: <a href="mailto:NTP-Meetings@icf.com">NTP-Meetings@icf.com</a> by September 21, 2018.

Meeting Materials: The draft RoC monograph and preliminary agenda will be available on the NTP website at <a href="https://ntp.niehs.nih.gov/go/36051">https://ntp.niehs.nih.gov/go/36051</a>. The draft RoC monograph should be available by August 24, 2018. Additional information will be posted when available or may be requested in hardcopy, contact Kate Helmick by phone: (919) 293-1673 or email: <a href="https://ntp-Meetings@icf.com">NTP-Meetings@icf.com</a>. The preliminary meeting agenda will be available on the meeting web page and will be updated one week before the meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on the RoC: Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. For each listed substance, the RoC contains a substance profile, which provides information on cancer studies that support the listing—including those in humans and animals and studies on possible mechanisms of action, information about potential sources of exposure to humans, and current Federal regulations to limit exposures. The 14th RoC, the latest edition, was published on November 3, 2016 (available at https://ntp.niehs.nih.gov/go/roc14).

Background Information on NTP Peer-Review Panels: NTP panels are technical,

scientific advisory bodies established on an "as needed" basis to provide independent

scientific peer review and advise NTP on agents of public health concern, new/revised

toxicological test methods, or other issues. These panels help ensure transparent,

unbiased, and scientifically rigorous input to the program for its use in making credible

decisions about human hazard, setting research and testing priorities, and providing

information to regulatory agencies about alternative methods for toxicity screening. NTP

welcomes nominations of scientific experts for upcoming panels. Scientists interested in

serving on an NTP panel should provide their current curriculum vitae to Kate Helmick

by email: NTP-Meetings@icf.com. The authority for NTP panels is provided by 42

U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is

governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2),

which sets forth standards for the formation and use of advisory committees.

Dated: August 8, 2018

Brian R. Berridge,

Associate Director,

National Toxicology Program.

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6